K012751
1 OF 3

NOV 1 4 2001

510(k) SUMMARY

Name of 510(k) sponsor:	Orquest, Inc.
Address:	365 Ravendale Drive Mountain View, CA 94043 Telephone: 650 237.4800 Fax: 650 903.1903:
Contact information:	Kristine F. Lahman Telephone: 650-237-4852 Fax: 650-903-0157
Date summary prepared:	August 15, 2001
Proprietary name of device:	HEALOS® Bone Graft Material
Generic/classification name:	Bone void filler
Product code (classification):	MQV (not classified)

Legally Marketed Predicate Devices:

Vitoss Scaffold Synthetic Cancellous Bone Void Filler (K994337);
Pro Osteon Implant 500R Resorbable Bone Graft Filler/Bone Graft Material; 200R Resorbable Bone Graft Material (K980817, K990131, K0000515);
Bio-Oss Collagen (K974399); and
Collagen Periodontal Membrane (K003339)
Collagraft Strip Bone Graft Matrix (K000122)

Device Description:

HEALOS® Bone Graft Material (HEALOS) is a mineralized collagen matrix processed into lyophilized strips or pads for surgical implantation. The principal components of HEALOS are Type I bovine collagen and hydroxyapatite. HEALOS is approximately 30% mineral by weight. The collagen is processed prior to mineralization using aqueous and organic purification steps to reduce lipids, salts, and endotoxins. Hydroxyapatite coats the surface of the collagen fibers by the controlled addition of calcium chloride, sodium phosphate, and sodium hydroxide. The mineralized collagen fibers are fixed into a three dimensional, open-cell matrix.

HEALOS is provided as a sterile, dry material that must be hydrated with autogenous bone marrow at the point of use. HEALOS can be cut into shapes optimized for a specific population and is designed to retain its shape and physical integrity following implantation into a bony site. HEALOS is fully resorbed during the natural process of bone formation and remodeling.

Intended Use

HEALOS, combined with autogenous bone marrow, is intended for use in filling bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. HEALOS should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously. The product provides a bone void filler that is resorbed and remodeled into new bone as part of the natural healing process.

Technological Characteristics

The intended use, product design, composition, physical structure, and target population of HEALOS are substantially equivalent to the FDA cleared and legally marketed predicate devices named in the chart below as follows.

- HEALOS and the predicate devices, Vitoss (K994337) and Pro Osteon (K980817, K990131, and K000515) are intended for the same use and target populations.
- HEALOS and the predicate devices are sterile and are all matrices that provide an environment for new bone ingrowth.
- Like Collagraft (K000122) and Bio-Oss Collagen (K974399), HEALOS is a combination of collagen and bone mineral. Although Bio-Oss has a smaller proportion of collagen than HEALOS (10% vs. 70%), there are other dental bone filling augmentation materials that are comprised entirely of collagen (i.e., the named predicate device, Collagen Periodontal Membrane, K00339).
- HEALOS and the predicate devices are resorbed following implantation. The extent and rate of absorption differ between HEALOS and the predicate devices and across predicate devices. These differences in resorption rate do not present safety or efficacy issues because HEALOS is intended to fill bony gaps and defects and not to impart mechanical strength to osseous defects.
- Although HEALOS differs from Vitoss, Pro Osteon, and Bio-Oss with regard to form (strips vs. granules), it is similar in form to the Collagen Periodontal Membrane.

Testing

HEALOS has undergone material characterization testing (calcium and sodium content; mineral content; metal content; residual aldehyde content; mechanical stability of hydroxyapatite coating;

X-ray diffraction; and mercury porosimetry); performance testing (pH measurement; in vitro solubility; and in vivo testing (rabbit radial defect model, rat cranial defect model, spinal fusion models)); biocompatibility testing (intracutaneous toxicity; systemic toxicity; genotoxicity; cytotoxicity; sensitization; and bone implantation); and clinical testing.

Conclusions

The results from these tests support the substantial equivalence of HEALOS Bone Graft Material to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2001

Ms. Kristine F Lahman
Orquest, Inc.
365 Ravendale Drive
Mountain View, California 94043

Re: K012751
Trade/Device Name: HEALOS® Bone Graft Material
Regulatory Class: Unclassified
Product Code: MQV and LYC
Dated: August 15, 2001
Received: August 16, 2001

Dear Ms. Lahman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

NOV 1 4 2001

INDICATIONS FOR USE STATEMENT

Applicant: Orquest, Inc.

510(k) Number: K012751

Device Name: HEALOS® Bone Graft Material

Indications for Use: HEALOS® Bone Graft Material ("HEALOS"), combined with autogenous bone marrow, is intended for use in filling bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. HEALOS should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously. The product provides a bone void filler that is resorbed and remodeled into new bone as part of the natural healing process.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

~~Participation~~ Prescription Use ✓ or Over-the Counter Use ____

for Mark N Melkerson

(Division Sign-Off)

Div[illegible] Restorative and [illegible]logical Devices

510(k) Number K012751